UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO CLASS 1 RESIDENTS OF THE COMMONWEALTH OF MASSACHUSETTS	

THE J&J DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR POST-REMAND MOTION FOR SUMMARY JUDGMENT AGAINST CLASS 1 RESIDENTS OF THE COMMONWEALTH OF MASSACHUSETTS

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MISCELLANEOUS

Johnson & Johnson, Centocor, Inc., and Ortho Biotech Products, LP (the "J&J Defendants") submit this memorandum of law in support of their motion for summary judgment against Class 1 residents of the Commonwealth of Massachusetts.

Preliminary Statement

This motion by the J&J Defendants is one of two motions for summary judgment with respect to the claims asserted by members of Class 1. This motion seeks summary judgment with respect to residents of Massachusetts. The J&J Defendants have moved separately with respect to class members who reside in other states and in the District of Columbia.

Abbreviated Procedural History

Class 1 was certified on January 30, 2006. *In re Pharm. Indus. Average Wholesale Price Litig.* ("*In re AWP*"), 233 F.R.D. 229 (D. Mass. 2006). For the J&J Defendants, Class 1 is a "nationwide" class of natural persons who made, or who incurred an enforceable obligation to make, a co-payment for Procrit® or Remicade® based on AWP. *Id.* at 230. The residents of nine states—Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana, and Virginia—were excluded from Class 1 on the grounds that the consumer protection statutes in those states do not permit class actions. *Id*. The claims of Massachusetts residents are governed by Mass. Gen. Laws Ch. 93A, *et seq.* *Id*.

Two sets of class representatives were designated to represent the interests of the J&J Defendant Subclasses. James and Therese Shepley represent the J&J Subclass with respect to Procrit; Larry Young on behalf of the Estate of Patricia Young represents the J&J Subclass with respect to Remicade. *Id.*

The parties filed cross-motions for summary judgment with respect to Classes 1 and 2 in March 2006. In its summary judgment ruling, the Court construed the term "average wholesale price" in the Balanced Budget Act of 1997 according to its "plain meaning" to include discounts and rebates. *In re AWP*, 460 F. Supp. 2d 277, 287-88 (D. Mass. 2006). The Court granted defendants' summary judgment motion with respect to all Medicare Part B drugs "furnished in 2004," because it found that when Congress passed the Medicare Prescription Drug, Improvement and Modernization Act ("MMA") in 2003, it understood that "AWP was different than average sales price and was not reflective of actual prices in the marketplace." *Id.* at 288. The Court denied the parties' summary judgment motions in all other respects, reserved decision on the remainder of the parties' motions, and said it would "address the remaining issues raised by the summary judgment papers at trial." *Id.*

The Track One bench trial was conducted in November and December of 2006. The trial was limited to claims by Medi-Gap insurers in Class 2, and consumers and TPPs in Class 3. The Court issued its Findings and Conclusions in June 2007. *In re AWP*, 491 F. Supp. 2d 20 (D. Mass. 2007).

The Court ruled that the J&J Defendants had not violated Ch. 93A with respect to Procrit because, as plaintiffs conceded, the spreads on Procrit were consistently below Dr. Raymond Hartman's 30% liability yardstick, and usually below 25%. *Id.* at 56, 104. Dr. Meredith Rosenthal, acknowledged that Procrit was one of the drugs for which AWP-based reimbursement "seems to work well because the AWP closely tracks the ASP." *Id.* at 104.

The Court also ruled that the J&J Defendants had not violated Ch. 93A with respect to Remicade. Although the Court found that Remicade's WAC-to-AWP spread was 30%, rather than the customary 20% or 25%, Centocor did not discount Remicade to physicians.

Id. at 57. The absence of any discounting meant that Remicade's "AWP closely tracked ASP throughout the [class] period, and the spreads were all at or about 30%." *Id.* at 104. Thus, as to Remicade, "there were no secret or deceptive spreads." *Id.* Although the Court said it was a "close call," it rejected plaintiffs' argument that Remicade should be subject to a unique liability yardstick of 25% because the incremental 5% markup violated Ch. 93A. *Id.*

Of final note, the Court also rejected plaintiffs' theory that Class 2 Medi-Gap payors should be allowed to recover based on a *per se* or "zero tolerance" liability theory. *Id.* at 97 ("I reject plaintiffs' zero tolerance approach to liability and damages in Class 2.") Plaintiffs argued that *per se* liability should apply to Class 2 because their co-payments were set by statute. They urged the Court to reach this conclusion based on three sources of law: the Federal Trade Commission Act, regulations published by the Massachusetts Attorney General, and the Medicare statute. *Id.* at 82. The Court rejected these arguments, finding that these statutes and regulations did not apply to defendants' conduct, because defendants did not advertise their prices to consumers and the Medicare statute was not a consumer protection statute within the meaning of the Massachusetts Attorney General's regulations. *Id.* at 84-85.[1]

[1]In its June 2007 liability decision the Court noted that government knowledge of the 20 or 25 percent markup between WAC and AWP was "arguably relevant in construing the meaning of the statutory term AWP." *In re AWP*, 491 F. Supp. 2d at 97 n.72. Nevertheless, the Court underscored its conclusion that Congress did not intend AWP to reflect any markup over average selling price the manufacturer chose, a view endorsed by the First Circuit Court of Appeals in its AstraZeneca opinion. *Blue Cross Blue Shield of Mass. v. AstraZeneca Pharm. LP*, 582 F.3d 156, 172 (1st Cir. 2009) (the 1998 Medicare statute "in no way countenanced spreads in excess of the industry expectations") However, because this Court had rejected plaintiffs' *per se* liability theory in favor of Dr. Hartman's 30% liability yardstick, the First Circuit said it was "unnecessary to decide whether the term 'average wholesale price' admits of no spreads at all, as the district court appears to have concluded in its November 2006 order, or whether instead it admits of modest spreads (such as those created by prompt-pay discounts or formulaic markups from other published prices)." *Id.* For this reason, the First Circuit concluded that "we need not decide whether the district court's ultimate 'plain meaning' analysis of 'average wholesale price' was correct, for the district court did not rely on this specific definition as a trigger for liability under Chapter 93A." *Id.* at 171.

Two weeks after the Court issued its Findings and Conclusions, during a pre-trial conference involving Bristol-Myers Squibb, plaintiffs' attorney, Steve W. Berman, asked the Court whether Dr. Hartman's 30% liability yardstick applied to the claims by consumers in Class 1. Exh. 1[2] (07/03/07 Hrg. Tr.) at 8:19-11:3. The Court responded that the 30% yardstick did apply to Class 1. *Id.* Mr. Berman said plaintiffs felt a different standard should apply to consumers "because there's no evidence that they had any knowledge of the so-called industry norm of 20, 25 percent." *Id.* The Court responded: "Well, I ruled to the contrary and I don't accept that position. And, I thought it was clear. If not, I'm making it clear now." *Id.*

The Track One Defendants moved for entry of judgment pursuant to Fed. R. Civ. P. 54(b). Dkt. # 4616. The Court granted the motion. The Court explained that judgment in favor of the J&J Defendants was appropriate under Ch. 93A with respect to Classes 2 and 3, because the spreads on Procrit and Remicade "never substantially exceeded the range of spreads generally expected by the industry and government." Exh. 2 (11/20/07 Findings & Order) at 5. The Court entered judgment against Class 1 "for the same reason." *Id.*

On December 19, 2007, one of plaintiffs' attorneys, Donald E. Haviland, Jr., filed a Notice of Appeal on behalf of Larry Young and Therese Shepley. Exh. 3 (12/19/07 Notice of App.). His fellow class counsel did not sign or join in the Notice of Appeal. *Id.* Later, after the Court removed Mr. Haviland as class counsel, the remaining class counsel were granted leave to pursue the appeal. Exh. 4 (2/15/08 1st Cir. Order of Court).

The First Circuit Court of Appeals decided the appeal by Mr. Young and Ms. Shepley on September 28, 2009. *Shepley v. Johnson & Johnson*, 582 F.3d 231 (1st Cir. 2009).

[2] All "Exh." cites are to the exhibits to the November 23, 2009 Declaration of Andrew D. Schau in support of this Motion.

The Court of Appeals vacated the Class 1 judgment and remanded the case to this Court because it said it "lack[ed] a clear understanding of both the scope of the district court's judgment and the reasons for the judgment." *Id.* at 237. It invited the Court to provide "additional explanation of its judgment." *Id.*

The Court of Appeals expressed a concern that fact findings made by the Court after a bench trial could not be applied to Class 1 in states where the relevant consumer protection statutes provide for a jury trial. *Id.* at 236. The Court of Appeals made clear, however, that this concern was inapplicable to Class 1 residents of the Commonwealth of Massachusetts, because Ch. 93A does not provide the right to a jury trial. *Id.* at 237. The Court of Appeals also stated that its decision should not be interpreted necessarily to require a trial of the Class 1 consumer claims in other states, or to preclude this Court from granting judgment in favor of the J&J Defendants based on a properly framed motion for summary judgment. *Id.* The Court of Appeals said Class 1 plaintiffs should be allowed to make a proffer of evidence concerning their "expectations with respect to reasonable spreads" between average selling prices and AWP. *Id.*

Summary of Argument

This Court has already heard all of the evidence and made all of the fact findings needed in order to enter summary judgment in favor of the J&J Defendants with respect to Class 1 residents of Massachusetts. Indeed, at the status conference on October 8, 2009 the Court stated that its Class 1 judgment was intended to apply to Massachusetts consumers. Exh. 5 (10/08/09 Hrg. Tr.) at 7. As to those consumers, the Court's findings after a bench trial are dispositive, because Ch. 93A does not provide a right to a jury trial. Thus, in Massachusetts,

there is no possibility or occasion for a jury to decide the facts differently than they have already been decided by the Court.

There is also no reason to hold an additional bench trial with respect to the "consumer expectation" issue identified by the Court of Appeals. The existing trial and summary judgment record conclusively establishes that consumers who paid for Part B medications had no expectation whatsoever concerning the relationship between average selling prices and AWP. In fact, it is undisputed that consumers knew nothing about AWP, as none of defendants' pricing communications were directed to consumers. *In re AWP*, 491 F. Supp. 2d at 38, 83-84. Moreover, the consumers' co-payment amounts were set by federal regulation or statute, not by individual negotiations. Thus, the consumers' lack of knowledge concerning AWP had no possible bearing on the amount of their co-payments. Where, as here, the government set the co-payment amount, the relevant "expectations" to consider in assessing liability for Class 1 should be the expectations of the government officials and legislators who chose AWP as the basis for payment. As this Court has already found, these officials expected spreads between average selling prices and AWP in the range of approximately 30%. In short, the consumers' lack of knowledge of spreads, and the government's knowledge of spreads in the range of 30%, are both conceded. There are no fact issues left to try.

ARGUMENT

I. SUMMARY JUDGMENT IS APPROPRIATE AGAINST CLASS 1 RESIDENTS OF THE COMMONWEALTH OF MASSACHUSETTS

A. Plaintiffs Conceded, and the Court Found, That Industry and Government Expected Spreads in the Range of 30 Percent

This case was never about whether industry and government knew that there were "modest spreads (such as those created by prompt-pay discounts or formulaic markups from other published prices)." *Blue Cross Blue Shield of Mass. v. AstraZeneca Pharm. LP*, 582 F.3d

156, 172 (1st Cir. 2009). Rather, the critical dispute was whether "the government and industry were aware of the *magnitude* of the spread." *In re AWP*, 230 F.R.D. 61, 71 (D. Mass. 2005) (emphasis added); *see also* Exh. 6 (4/6/06 Hartman Decl. in Opp. to S.J.) ¶¶ 5-8 ("Liability is alleged not because AWP exceeds the ASP; rather liability is alleged because it exceeded ASP by the unreasonably and unexpectedly substantial amounts reflected in the 'mega-spreads' recognized by [the Court] and Dr. Berndt."). Dr. Rosenthal testified that a drug's AWP should "track" its average selling price, but "not certainly [be] equal." Exh. 7 (11/27/06 Trial Tr.) at 71:1-6.

Plaintiffs conceded, and the Court found, that "it is undisputed that the market understood and expected a 20 to 25 percent formulaic markup from WAC to AWP." *In re AWP*, 491 F. Supp. 2d at 91; *see also id.* at 40 ("[T]hroughout the class period, most knowledgeable insiders understood that AWP did not reflect the average sales price to providers, but that it bore a formulaic relationship to WAC of a 20 to 25 percent markup."). Plaintiffs also conceded, and the Court found, that "payors were aware there was some discounting from WAC." *Id.* at 40. The Court endorsed Dr. Hartman's contention that the formulaic markup, coupled with modest discounts from WAC, resulted in a marketplace expectation of spreads in the range of approximately 30%. *Id.* at 92 (finding that Dr. Hartman's 30% yardstick was a reliable measure of marketplace expectations); *see also* Exh. 8 (11/21/06 Trial Tr.) at 120:17-23 (testimony by Dr. Hartman that his 30% yardstick generally reflected what "payors either understood or just basically took as for granted").

Plaintiffs conceded, and the Court found, that the government shared the market's understanding of spreads in the range of 30%. *In re AWP*, 491 F. Supp. 2d at 32; *see also id.* at 40 (citing Dr. Hartman's testimony that "government [and] policy makers" expected that "AWP

did not exceed the average sales price by more than 30 percent"); Exh. 9 (11/20/06 Trial Tr.) at 118:19-21 (testimony by Dr. Hartman that "[t]he government has set reimbursement rates that reflect an understanding that is comparable to what I would say is – in my yardsticks"); *id.* at 119:17-25, 120:1-19 (testimony by Dr. Hartman that his 30% liability yardstick was appropriately applied to Medicare); H.R. Rep. No. 108-178, pt. 2, at 194, 197-98 (2003) ("Congress has long recognized AWP is a list price and not a measure of actual prices.").[3]

B. Plaintiffs Conceded, and the Court Found, That the Spreads on Procrit and Remicade Were Approximately 30 Percent or Less

The spreads on Procrit were always less than 30%. *In re AWP*, 491 F. Supp. 2d at 56, 104. The spreads on Remicade "hovered very near to 30% throughout the class period." *Id.* at 58. For both drugs, the published AWP closely tracked the average selling price. *Id.* at 104. The Court found that the spreads on Procrit and Remicade "never substantially exceeded the range of what was generally expected by the industry and the government." *Id.* at 31.

C. It Is Undisputed That Class 1 Consumers Did Not Know About AWP and Had No Expectations Concerning Reasonable Spreads

Although the First Circuit invited plaintiffs to proffer evidence about Class 1's expectations concerning reasonable spreads, the record already establishes, and the Court has already found, that consumers knew nothing about AWP. As such, Class 1 had no expectations concerning the existence or magnitude of spreads between AWP and average selling prices.

[3] The Court's finding that the government expected moderate spreads is consistent with the government's position in the Lupron criminal prosecution. According to Michael K. Loukes, former Chief of the Health Care Fraud Unit for the U.S. Attorney's Office in Boston, Congress expected AWP to reflect a percentage markup over WAC. *See* Exh. 10 (6/24/04 Hrg. Tr., *United States v. MacKenzie*, CR-01-10350-DPW (D. Mass)) at 67:23-68:6 ("As a matter of fact, Your Honor, a historical fact … everybody got the spread between AWP and list price, the same 25 percent…. And the 25 percent, everyone gets that. That's there. *That's what Congress expected with AWP*." (emphasis added)).

The fact that consumers have never heard of AWP has never been disputed. From the outset, the Court's decision to certify a nationwide class of consumers was based, in part, on its observation that consumer co-payments were fixed by statute and, therefore, the consumers' knowledge of AWP (or, more precisely, their lack of knowledge of AWP) would be uniform across class members. Thus, in discussing the predominance requirement under Fed. R. Civ. P. 23(b)(3), the Court noted that:

> Defendants have spent little time challenging the predominance of factual issues with respect to consumers who co-pay for physician-administered drugs under Medicare Part B. Here, common factual issues predominate since a typical consumer *by statute* simply pays a percentage of AWP as a co-pay. There is therefore *no separate factual issue* regarding the knowledge and reliance of each class member.

In re AWP, 230 F.R.D. at 82 (emphasis added). The Court made similar statements in its choice of law analysis:

> However, in this context, where consumers … make a percentage co-payment based on the stated AWP, there is no indication that different definitions of reliance and causation will matter or cannot be resolved as a matter of law prior to trial.

Id. at 85.

These observations, which were instrumental to the Court's decision to certify a nationwide consumer class, proved prescient. Plaintiffs called two consumer witnesses at trial, Anna Choice and Rebecca Hopkins. Not surprisingly they had never heard of AWP. *In re AWP*, 491 F. Supp. 2d at 38. Ms. Choice testified she had no "knowledge regarding what AWP meant." Exh. 11 (11/07/06 Trial Tr.) at 74:13-15. Ms. Hopkins testified that she did not "know anything about AWP at all." *Id.* at 107:23-25.

The class representatives designated to pursue consumer claims against the J&J Defendants gave similar testimony at their depositions. Mr. Young, the class representative for

Remicade, testified that he never heard of AWP, and that he did not know how or by whom AWP was calculated. Exh. 12 (11/09/05 Young Dep. Tr.) at 61. Mr. Shepley, the class representative for Procrit, also testified that he was not familiar with AWP. Exh. 13 (11/11/05 Shepley Dep. Tr.) at 29:8-14.

Obviously, consumers who have never heard of AWP cannot possibly have formed any "expectations with respect to reasonable spreads." *Shepley v. Johnson & Johnson*, 582 F.3d at 237. Moreover, since their co-payment obligations were set by federal regulation in 1991[4] and by federal statute in 1997,[5] their lack of expectations concerning spreads had no effect on the amount of their co-payments. *See In re AWP*, 230 F.R.D. at 71 (noting that the 80/20 payment allocation between Medicare and Medicare beneficiaries is fixed by 42 U.S.C. § 13951(a)(1)(S)). In short, the absence of any consumer expectation concerning spreads had no bearing whatsoever on the amount the federal government required them to pay for Part B medications.

D. The Government's Expectation Concerning Reasonable Spreads Should Be the Controlling Expectation for Assessing Liability in Class 1

Since the consumers' co-payment was fixed by regulation or statute, it stands to reason that the liability yardstick for Class 1 should be based on what HCFA and Congress knew and expected when they selected AWP as the reimbursement benchmark, not what consumers knew and expected. Indeed, in the Court's 2006 summary judgment ruling, the Court granted summary judgment against Class 1 with respect to all drugs "furnished in 2004" (when reimbursement was set at 85% of AWP) because, when Congress enacted the MMA in 2003,

[4] Medicare Program, Fee Schedule for Physician Services, 56 Fed. Reg. 59,502 (Nov. 25, 1991).

[5] Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251.

"Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace." *In re AWP*, 460 F. Supp. 2d at 288. Thus, the Court has already determined that where an AWP-based co-payment is set by statute, the yardstick for liability and damages is based on what *Congress understood* about AWP, not what *consumers understood* about AWP. *Id.*

This result makes sense. Plaintiffs contended that HCFA and Congress chose AWP as the Medicare reimbursement benchmark with the expectation that the difference between a drug's average sales price and AWP would not exceed approximately 30%. The Court agreed with this contention, concluding that the AWPs for Procrit and Remicade were not excessive because they were within the range that HCFA and Congress expected. *In re AWP*, 491 F. Supp. 2d at 56, 104. It follows that neither the Medicare program (which paid 80% of the reimbursement amount), nor Medicare beneficiaries (who paid 20%), paid more for Procrit and Remicade than Congress intended them to pay. Put differently, for drugs with moderate spreads within the range that HCFA and Congress expected, the government was not duped, and the percentage co-payments that the government assigned to Medicare beneficiaries were not excessive. Indeed, Dr. Hartman conceded at trial that application of his 30% yardstick to Procrit and Remicade yielded $0 in damages for Medi-Gap insurers in Class 2. Exh. 14 (12/11/06 Trial Tr.) at 95:1-6. By definition, the same 30% yardstick would yield $0 in damages for Medicare beneficiaries in Class 1.

It is perfectly appropriate to look to the government's understanding of AWP to determine the liability standard for Medicare beneficiaries in Class 1. Congress enacted the Medicare program for the benefit of consumers in Class 1. *In re AWP*, 460 F. Supp. 2d at 279. These consumers knew nothing about AWP. They depended on the federal government to set

the reimbursement rate and impose appropriate statutory co-payments. As Dr. Gaier testified, "individual Medicare beneficiaries are in some sense protected by Medicare. I mean, they don't go in and choose the amount of their reimbursement. It's set by Medicare . . . ." Exh. 15 (11/29/06 Trial Tr.) at 88:3-6.

An apt analogy is found in the "learned intermediary" rule concerning a pharmaceutical manufacturer's duty to warn about the potential adverse effects of its medications. Based on this doctrine, the duty to warn runs to the physician, not to the patient. As the First Circuit Court of Appeals explained in *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992), "[t]he rationale underlying the prescription drug rule is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly." (citing *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir.), cert. denied, 504 U.S. 956, 112 S. Ct. 2304, 119 L. Ed. 2d 226 (1992)).

Here, government officials chose AWP knowing that it was based on a fixed markup over WAC. These officials stand between the manufacturer and the consumer because they were in the best (indeed only) position to evaluate whether AWP was an appropriate reimbursement benchmark. Of course, based on the logic of the Court's 2007 liability opinion, if the manufacturer duped the government by creating "mega-spreads" that were not within the expected range, then the manufacturer can be held liable for taking unfair advantage of the government's reimbursement system. *In re AWP*, 491 F. Supp. 2d at 31. But if, as in the case of the J&J Defendants, the manufacturer's spreads were not excessive, then the government was not

duped, and neither the Medicare program nor Medicare beneficiaries can be said to have "overpaid" for the drug.

Moreover, if the Court were to find that the consumer's lack of knowledge about spreads gives rise to potential liability for drugs with spreads within the range of government expectations, then liability could attach anytime the government elects to reimburse a provider at a premium over acquisition cost. This would include, for example, the current reimbursement system based on average sales price. Under the current system, Congress decided to give physicians a statutory margin of six percent over average sales price. *In re AWP*, 460 F. Supp. 2d at 283 & n.6. Consumers, presumably, are not aware of this "spread," and many of them might credibly claim that they assume physicians are reimbursed at no more than their acquisition cost. It would nevertheless be absurd to conclude that such consumers, because they are unaware of the six percent margin, would have a claim against the pharmaceutical manufacturer. If the drug's spread is within the range that the federal government expected, consumers should not have a cause of action under Ch. 93A.

E. The Other Liability Factors Under Ch. 93A Do Not Provide Any Reason To Deny Summary Judgment

The evidence presented at the bench trial on Classes 2 and 3 enabled the Court to fully evaluate each of the liability factors identified in its June 2007 decision. Although the "most important" factor—whether the spreads on Procrit and Remicade exceeded approximately 30%—was undisputed, the facts relating to the other, less important liability factors were hotly contested. Notably, the Court resolved nearly all of those fact disputes *against* the J&J Defendants and in favor of plaintiffs. For example, the Court found that J&J Defendants' conduct was "at times troubling," that they sometimes "marketed the spread," etc. *In re AWP*, 491 F. Supp. 2d at 31, 103-04.

This is not the occasion to revisit the Court's findings of fact. Suffice it to say that the J&J Defendants do not necessarily agree with them.[6] However, disagreements over the Court's findings are irrelevant to whether the J&J Defendants are entitled to summary judgment. If the Court had instead resolved these fact disputes in favor of the J&J Defendants, the outcome of the trial would have been the same. Furthermore, conduct such as "marketing the spread," even if it is somehow "unfair," is not legally actionable if it does not cause consumers to suffer a cognizable loss. *See Hershenow v. Enter. Rent-A-Car Co. of Boston, Inc.*, 445 Mass. 790, 791, 840 N.E.2d 526, 528 (2006) ("Proving a causal connection between a deceptive act and a loss to the consumer is an essential predicate for recovery under our consumer protection statute [Ch. 93A]."). So long as plaintiffs were paying no more than what the government intended, they did not suffer a cognizable loss. Thus, consideration of the secondary liability factors identified in the Court's June 2007 decision does not provide a reason to deny summary judgment.

F. The Liability Standard Applied in the Track One Trial Was the Standard Applicable to Class 1

Massachusetts plaintiffs have an easier burden establishing liability under § 9 of Ch. 93A than they do under § 11. Under § 11, in order for a defendant's conduct to be unfair, plaintiffs must prove that it attained a particular "level of rascality" or had "an extortionate quality that gives it the rancid flavor of unfairness." *See Commercial Union Ins. Co v. Seven Provinces Ins. Co.*, 217 F.3d 33, 40 (1st Cir. 2000) (internal citations omitted). Plaintiffs were not required to make such a showing in the Track One trial because the Court assessed defendants' liability under the more lenient standard in § 9. *In re AWP*, 491 F. Supp. 2d at 80-82, 93-94. The case was thus decided based on the same liability standard that applies to

[6] The J&J Defendants wish to preserve, to the maximum extent possible, their right to object to or appeal from any ruling they believe was erroneous.

consumers in Class 1. *C.f. id*. at 80 n.49, 82 ("Class 3 consumers who made co-payments clearly have a claim under § 9.")

CONCLUSION

The alternative to summary judgment with respect to Class 1 consumers in Massachusetts would be a second bench trial on issues that have already been tried and decided. Such an exercise would be pointless and wasteful. The issue the First Circuit Court of Appeals flagged in its opinion—consumer expectations concerning reasonable spreads between average selling prices and AWP—does not merit a second bench trial, as it is undisputed that consumers had no spread-related expectations whatsoever. Moreover, this Court has already found in its 2006 summary judgment decision that in the circumstance where the co-payment amount is set by federal statute, the yardstick for liability and damages should be determined by reference to what the government knew, not what consumers knew. Finally, the Court has stated that it intended to apply Dr. Hartman's 30% yardstick to Massachusetts consumers in Class 1, a standard that inevitably spells the end of the case against the J&J Defendants under Ch. 93A.

Accordingly, the J&J Defendants respectfully request that the Court enter summary judgment in their favor against the members of Class 1 who reside in the Commonwealth of Massachusetts.

Dated: November 23, 2009

/s/ Andrew D. Schau

Andrew D. Schau
Adeel A. Mangi
Elizabeth Shofner
Michael Jacobsohn
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000
Attorneys for the J&J Defendants

CERTIFICATE OF SERVICE

I certify that on November 23, 2009 a true and correct copy of the foregoing was delivered via electronic service to all counsel of record pursuant to Case Management Order No. 2.

/s/ Andrew D. Schau
Andrew D. Schau